UNITED STATES
ENVIRONMENTAL PROTECTION
AGENCY

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Solid Waste and
Emergency Response

EPA 000-0-99-000
OSWER 0000.0-000
PB99-000000
www.epa.gov/superfund/pubs.ht

December 1999

Superfund

Risk Assessment Guidance for Superfund:

Volume 3 - (Part A, Process for Conducting Probabilistic Risk Assessment)

Draft

Printed on Recycled Pape

Publication 0000.0-000

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Draft

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DISCLAIMER

This document provides guidance to EPA staff. It also provides guidance to the public and to the regulated community on how EPA intends that the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) be implemented. The guidance is designed to describe EPA's national policy on the process for conducting probabilistic risk assessment for Superfund. The document does not, however, substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA may change this guidance in the future, as appropriate.

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations and regulatory policies that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This guidance document does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. As explained above, the guidance document does not impose legally-binding requirements on the States. It is a technical document that discusses a statistical approach for risk assessment that may be used at Superfund sites. Thus, the requirements of Section 6 of the Executive Order do not apply to this guidance document.

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ACRONYMS AND ABBREVIATIONS

AM	Arithmetic mean
ARARs	Applicable or relevant and appropriate requirements
AT	Averaging time
AWQC	Ambient water quality criterion
BCa	Bias correction acceleration method
BMD	Benchmark dose
BTAG	Biological Technical Assistance Group
BW	Body weight
C	Concentration
CAG	Community advisory group
CDF	Cumulative distribution function
CI	Confidence interval
CIC	Community involvement coordinator
CIs	Confidence intervals
CLT	Central limit theorem
CQR	Continuous quadratic regression
CSF	Cancer slope factor
CTE	Central tendency exposure
CV	Coefficient of variation
DQO	Data quality objectives
EC_0	Exposure concentration that produces zero effect
ED	Exposure duration
ED_{10}	Dose that causes a 10% effect
EC_{20}	Concentration that causes a 20% effect
EF	Exposure frequency
EPA	U.S. Environmental Protection Agency
EPC	Exposure point concentration
ERA	Ecological risk assessment
ERAF	Risk Assessment Forum
ERAGS	Ecological risk assessment guidance for Superfund
EVIU	Expected value of including uncertainty
EVOI	Expected value of information
EVPI	Expected value of perfect information
EVSI	Expected value of sample information
GM	Geometric mean
HHEM	Human health evaluation manual
HI	Hazard index
HQ	Hazard quotient
LADD	Life-time average daily intake
LCL	Lower confidence limit
LED_{10}	Lowest effect dose - lower confidence bound for dose that causes a 10% effect
LHS	Latin hypercube sampling
LOAEL	Lowest-observed-adverse-effect level
MCA	Monte Carlo analysis

MCL	Maximum contaminant levels
MDC	Maximum detected concentration
MEE	Microexposure event
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NOAEL	No-observed-adverse-effect level
QAPP	Quality assurance project plan
OLS	Ordinary least squares
PBPK	Physiologically-based pharmacokinetic
PDF	Probability density function
PPT	Parts per trillion
PRA	Probabilistic risk assessment
PRG	Preliminary remediation goal
PRP	Potentially responsible party
RAGS	Risk assessment guidance for Superfund
RCRA	Resource Conservation and Recovery Act
RfC	Reference concentration
RfD	Reference dose
RG	Remediation goal
RME	Reasonable maximum exposure
ROD	Record of decision
RPSS	Relative partial sum of squares
RPM	Remedial project manager
RSS	Regression sum of squares
SCM	Site conceptual model
SD	Standard deviation
SMDP	Scientific/Management Decision Point
SR	Sensitivity ratio
SSE	Sum of squares due to error
SSR	Squares due to regression
SST	Sum of squares
TAG	Technical assistance grant
TOSC	Technical outreach services for communities
TRV	Toxicity reference value
TSS	Total sum of squares
UCL	Upper confidence limit
VOI	Value of information

ACKNOWLEDGMENTS

This manual was developed by EPA's Office of Emergency and Remedial Response. A number of EPA regional and Headquarters technical staff participated in the Workgroup (see below) that developed the RAGS Vol. 3 approach presented in this manual. In addition, numerous individuals from Superfund and other program offices within the Agency provided useful comments during the internal peer review process.

ISSI Consulting Group and Syracuse Research Corporation provided technical assistance to EPA in the development of the manual, under contract No. SBAHQ-97-D.

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About the Revision

What it is EPA's *Process for Conducting Probabilistic Risk Assessment* is an update of the 1989 *Risk Assessment Guidance for Superfund (RAGS)*. It is Volume 3, an update to the existing two-volume set of RAGS. Volume 3 Part A provides policy and guidance on conducting probabilistic risk assessment for both human and ecological receptors.

Who it's for RAGS Vol. 3 is written primarily for risk assessors. Risk assessment reviewers, remedial project managers, and risk managers involved in Superfund site cleanup activities will also benefit from this addition to RAGS.

What's new Volume 3 provides guidance on applying probabilistic analysis to both human health and ecological risk assessment. New information and techniques are presented that reflect the views of the EPA Superfund program. A tiered approach is described for determining the extent and scope of the modeling effort that is consistent with the risk assessment objectives, the data available, and the information that may be used to support remedial action decisions at Superfund hazardous waste sites.

RAGS Vol. 3 Part A contains the following information:

- For the risk assessor -- updated policies and guidance; discussion and examples of Monte Carlo modeling techniques for estimating exposure and risk.

- For the risk manager and the remedial project manager -- An introduction to PRA, and a chapter on communicating risk estimates from PRA with the public.

Distribution RAGS Vol. 3 Part A is an EPA draft document that is being distributed for external review and public comment.

Send comments

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PREFACE

RAGS Vol. 3 Part A provides technical guidance on the application of probabilistic methods to human health and ecological risk assessment. This guidance focuses on Monte Carlo analysis (MCA) as a method of quantifying variability and uncertainty in risk. Primarily targeted toward the risk assessor, it is intended, both in content and format, to be most accessible to those readers who are familiar with risk assessment and basic statistical concepts. An attempt has been made to define all relevant technical terms using plain language and to illustrate concepts with examples. An exhibit at the beginning of each chapter provides definitions of terms used in that chapter. In addition, a comprehensive definition of terms is provided in Appendix A. Other useful information has been presented in exhibits placed throughout each chapter. Finger pointers emphasize important concepts and policy statements related to the use of probabilistic risk assessment (PRA). References are listed at the end of each chapter.

RAGS 3A was developed by the Probabilistic/Uncertainty Analysis Workgroup and the Ecological Risk Assessment Forum (ERAF); both groups are intra-Agency workgroups under the Risk Assessment Guidance for Superfund Administrative Reform activities. The guidance has undergone extensive review by Superfund and other programs within the Agency.

The Agency itself may incorporate probabilistic methods within the framework of site-specific risk assessments under fund-lead and Potentially Responsible Party (PRP)-lead risk assessments. PRPs may submit workplans for probabilistic risk analyses for review during the risk assessment process or as required under legal agreements. Similarly, when EPA chooses to use PRA for an EPA-lead risk assessment, a PRA workplan will assist in directing the EPA or contractor work on the site. Workplans can not only direct contractor activities on a risk assessment, but they also provide an opportunity to obtain internal feedback from knowledgeable EPA staff. EPA strongly recommends that PRPs involve the Agency in all decisions regarding the planning, submittal, and technical details of any PRA. Coordinating with EPA early in the process will ensure that PRAs conform to the recommended guidelines as part of the Superfund risk assessment process for protecting human and ecological health.

The development of a PRA will involve significant investment of time by the risk assessor and Remedial Project Manager to determine the extent and scope of the assessment. A tiered approach to PRA is advocated, beginning with evaluating the results of a point estimate approach. Important considerations include the time required to perform the PRA, the additional resources involved in developing the PRA, the quality and extent of data on exposure that will be used in the assessment, and the value added by conducting the PRA. Project scoping is an essential component of all risk assessments, especially PRA.

Necessarily, the performance of a PRA is computer intensive. A number of commercial software packages are mentioned in this guidance. Any mention or use of a particular product does not constitute an endorsement of that product by the Agency.

The term risk manager is used in this guidance to refer to individuals or entities that serve as the decision makers at hazardous waste sites. The term is used to emphasize the separation between risk assessment and risk management activities. Risk managers may include individual remedial project mangers, site partnering teams, senior EPA managers (Section Chiefs, Branch Chiefs or Division Directors), or other decision makers. The Superfund program is also developing a general fact sheet that gives a broad overview of PRA. The fact sheet will be written to be accessible to a broader audience, including those who may be less familiar with PRA.

ELEMENTS OF RAGS VOL. 3, PART A

RAGS Vol. 3 describes the basic concepts of variability and uncertainty, presents simple examples of PRA, and highlights the major advantages and disadvantages of both point estimate and probabilistic approaches. A tiered or stepwise approach is presented for determining the type of modeling effort that is consistent with a particular risk assessment objective, the quality and extent of data available, and the information that may be used to support remedial action decisions.

RAGS VOL. 3 PART A PROVIDES…

- introductory and advanced statistical approaches for characterizing variability and uncertainty in exposure;
- use of Monte Carlo analysis (MCA) to quantify variability and uncertainty in risk;
- use of MCA to develop preliminary remediation goals (PRGs);
- definitions applicable to PRA presented at the beginning of each chapter;
- standardized documentation of MCA modeling assumptions and simulation results;
- ways to evaluate the quality of a PRA;
- interpretation and communication of PRA output; and
- the relationship between RAGS Vol. 3 and other EPA guidance on Superfund risk assessment.

RAGS Vol. 3 presents approaches for developing probability distributions, conducting sensitivity analyses, and using a variety of Monte Carlo simulation techniques. Monte Carlo analysis is the most widely used method of PRA, and is, therefore, the focus of this guidance. Some of the more complex modeling approaches, including two-dimensional MCA, Microexposure Event (MEE) analysis, Bayesian Monte Carlo analysis, and geostatistics, are presented in the appendices.

RAGS Vol. 3 discusses the use of PRA in human health and ecological risk assessment, with a focus on the following topics: characterizing a probability density function (PDF) for the concentration term; estimating the RME from a distribution of risk; presenting assumptions and results; developing and using a workplan and a checklist for reviewers; and distinguishing good from bad approaches.

RAGS Vol. 3 also provides guidance on the use of PRA in ecological risk assessment (Chapter 5). The general risk assessment approach and terminology unique to risk characterization for ecological receptors adheres closely to the recently issued Guidelines for Ecological Risk Assessment (U.S. EPA, 1998a).

Separate chapters are devoted to the use of probabilistic approaches to develop preliminary remediation goals (PRGs) (Chapter 7), and techniques for effectively communicating the results of PRA (Chapter 8).

INTRODUCTION

Purpose of RAGS Vol. 3

Risk Assessment Guidance for Superfund Volume 3: Part A (RAGS Vol. 3) addresses the technical and policy issues associated with the use of probabilistic risk assessment (PRA) in the U.S. Environmental Protection Agency (EPA) Superfund program. This guidance builds upon basic concepts of risk assessment outlined in RAGS Volumes 1 and 2 (U.S. EPA, 1989a, b; 1998b), recent guidance for ecological risk assessment (U.S. EPA, 1998a; 1999), and the Agency Probabilistic Analysis Policy document (U.S. EPA, 1997b). This guidance describes the use of PRA for both human health and ecological risk assessments. PRA is not a requirement, and may not be appropriate at many sites.

What is Probabilistic Risk Assessment (PRA)?

PRA is a risk assessment that uses probability distributions to characterize variability or uncertainty in risk estimates. PRA is best understood by comparing it to the more familiar point estimate risk assessment methodology. In a traditional point estimate risk assessment, a single value is chosen for each exposure variable. For example, in a drinking water exposure scenario, the common Reasonable Maximum Exposure (RME, see below) adult weighs 70 kilograms and drinks two liters of water a day. Probabilistic risk assessment differs from the point estimate approach by allowing a value to be chosen from a distribution of plausible values for an exposure variable. For example, some adults drink two liters of water a day, others drink three liters, and still others drink greater or lesser quantities. Some adults weigh 70 kilograms, and others weigh less or more than this amount. Variables that can assume different values for different people are referred to as a random or stochastic variables.

In PRA, one or more (random) variables in the risk equation is defined mathematically by probability distributions. Similarly, the output of a PRA is a range or distribution of risks experienced by the various members of the population of concern (Fig. A).

Monte Carlo analysis (MCA) is the most widely used method of PRA. In MCA, an exposure dose calculation is repeated thousands of times using statistical techniques to select random values for each exposure variable that is characterized by a probability distribution. The result, or output distribution, reflects the range of exposure doses that may exist at the site for the population being considered (Fig. A). This distribution of doses is then multiplied by the appropriate toxicity values to obtain a distribution of risks.

The results of MCA appear as a distribution of outcomes of the many individual risk calculations. The result or output distribution of MCA reflects the range and relative frequency of risks that may exist at the site for the population and the exposure-related activities being considered. Thus, PRA enables risk assessors to use statistical and mathematical techniques to obtain quantitative measures of both uncertainty and variability in risk estimates. The probabilistic risk estimate reflects the assumptions of the exposure model and the distributions used to characterize input variables of the model. The representativeness of the output is based on the representativeness of both the conceptual model and the information used to define the input distributions.

Variability and Uncertainty in Risk Assessment

When using the traditional point estimate approach for risk assessment, the Superfund program has sought to calculate multiple risk descriptors to characterize individual risks. The 1989 Risk Assessment Guidance for Superfund (Section 6.1.2 of U.S. EPA, 1989a) states that remedial decisions typically will be based on Reasonable Maximum Exposure or RME (the highest exposure that is reasonably expected to occur at a site). The intent of the RME is to estimate a conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures based on both quantitative information and professional judgment (Sections 6.1.2 and 6.4.1 of U.S. EPA, 1989a). In 1992, the Agency produced guidance that also called for a statement of confidence in the results of the risk assessment and a full discussion of the uncertainties (U.S. EPA, 1992b). This guidance introduced the term Central Tendency Exposure or CTE, which represents the level of exposure to an "average" member of the exposed population. Presenting risk estimates based on both the RME and CTE provides a *semi-quantitative* estimate of the variability of risks in the population. In the point estimate approach, uncertainty surrounding these risk estimates is typically discussed in a qualitative way.

RAGS Vol. 3 provides guidance on simulating the dose distribution for a population using PRA. Probabilistic methods provide a means of (1) obtaining risk estimates for individuals within the high-end range; and (2) quantifying the confidence or level of uncertainty in these risk estimates.

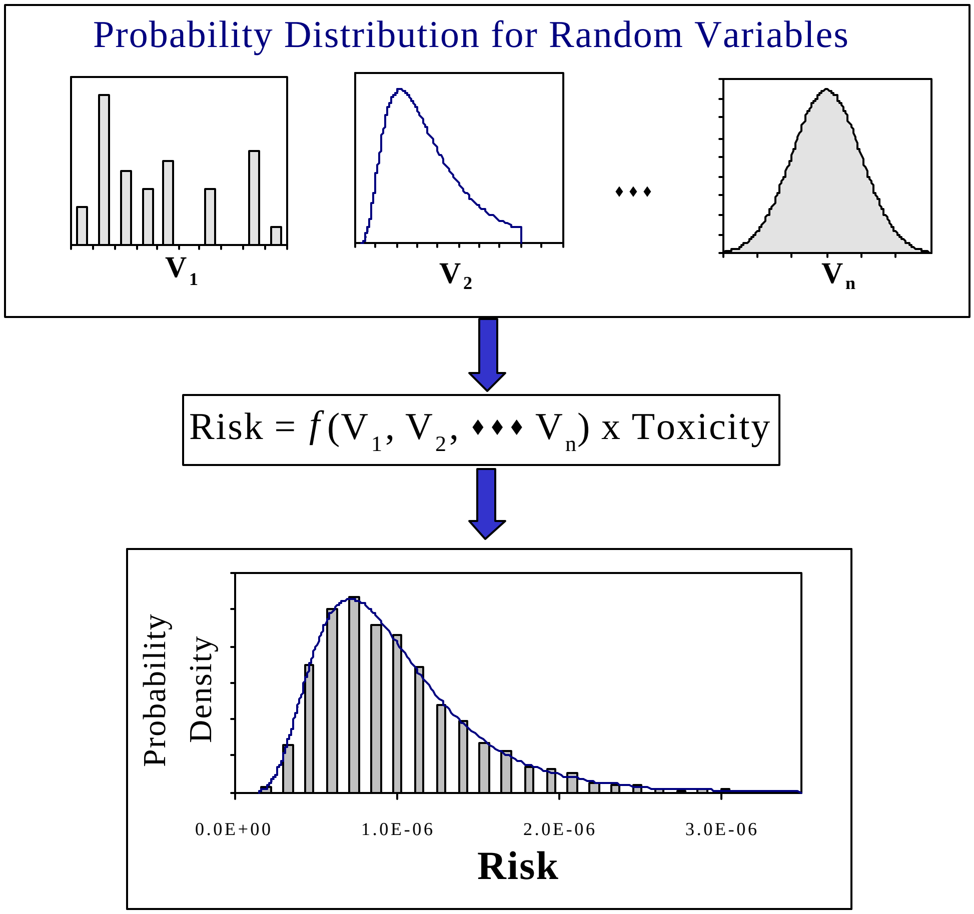

Figure A. Conceptual model of Monte Carlo analysis, the method of probabilistic risk assessment discussed in this guidance. Random variables (V_1, V_2,…V_n) refer to exposure variables (e.g., body weight, exposure frequency, ingestion rate, etc.) that are characterized by ranges or distributions. A unique risk estimate is calculated for each set of random values. Repeatedly sampling {V_i} results in a range or distribution of risk. The toxicity term is expressed as a point estimate for human health risk assessment, but may be expressed by a probability distribution for ecological risk assessment.

The evaluation of variability and uncertainty is an important component of the risk characterization of all risk assessments. As stated in the 1995 Risk Characterization memorandum from Administrator Carol Browner (U.S. EPA, 1995),

> *... we must fully, openly, and clearly characterize risks. In doing so, we will disclose the scientific analyses, uncertainties, assumptions, and science policies which underlie our decisions... There is value in sharing with others the complexities and challenges we face in making decisions in the face of uncertainty.*

In addition, the 1997 EPA Policy for Use of Probabilistic Analysis in Risk Assessment (U.S. EPA, 1997b) states:

> *It is the policy of the U.S. Environmental Protection Agency that such probabilistic analysis techniques as Monte Carlo analysis, given adequate supporting data and credible assumptions, can be viable statistical tools for analyzing variability and uncertainty in risk assessments.*

At present, probabilistic techniques for human health risk assessment are intended to apply to the exposure assessment, but not to the dose-response assessment. For ecological risk assessment, probabilistic techniques may be applied to both the exposure assessment and the toxicity assessment.

Advantages and Disadvantages of PRA for Remedial Decisions

The primary advantage of PRA within the Superfund program is that it gives a quantitative description of the uncertainties in risk estimates for both cancer and non-cancer health effects and ecological hazards. PRA may also provide a quantitative measure of variability in risk. The quantitative analysis of uncertainty and variability provides a more comprehensive characterization of risk than is possible in the point estimate approach.

Another significant advantage of PRA is the additional information and potential flexibility it affords the risk manager. The RME represents the highest exposure reasonably likely to occur (U.S. EPA, 1989a). Superfund remedy decisions are often based on an evaluation of the risk to the individual at the Reasonable Maximum Exposure (RME) level. When using PRA, the risk manager selects the RME from the high-end percentiles of risk, generally between the 90^{th} and 99.9^{th} percentiles - referred to as the RME range in this guidance. A recommended starting point for determining the RME risk from the RME range is the 95^{th} percentile of the risk distribution.

In many cases, a point estimate approach yields an RME risk estimate in the top 10% of the exposure distribution (i.e., $>90^{th}$ percentile). However, the point estimate approach cannot identify where the RME estimate lies in the high end of the risk distribution. Another advantage of PRA is that a more exact percentile of risk chosen for the RME will be known. Furthermore, in PRA, methods for sensitivity analysis are more reliable for identifying the variables and parameters that have the greatest influence on the risk estimates.

A point estimate approach should always be performed prior to considering a PRA. While PRA can provide a useful tool to characterize and quantify variability and uncertainty in risk assessments, it is not appropriate for every site. PRA generally requires more time, resources, and expertise on the part of the assessor, reviewer, and risk manager than a point estimate risk assessment. In addition, communicating the results of a PRA may be a challenge. If the additional information from a PRA is unlikely to affect the risk management decision, then it may not be prudent to proceed with a PRA. However, if there is a clear value added from performing a PRA, then the use of PRA as a risk assessment tool generally should be considered despite the additional resources that may be needed. The decision to use PRA is site-specific and is based on the complexity of the problems at the site and the quality and extent of site-specific data. RAGS Vol. 3 recommends a tiered approach (see Chapter 1) to risk assessment so that the scope of the assessment matches the scope of the site-specific problem being assessed. RAGS Vol. 3 provides general guidance to prevent misuse and misinterpretation of PRA. Topics covered in RAGS Vol. 3 include the mathematical and statistical techniques of PRA as well as the effective communication of the results of a PRA to a variety of audiences involved at Superfund sites.

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